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PATENT
Docket No. 018563-002800US

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Commissioner for Patents
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Alexandria, VA 22313-1450

On October 1, 2003

TOWNSEND and TOWNSEND and CREW LLP

By: _____
Jodie M. Rivas

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

PHAN, LOC X.

Application No.: 09/641, 208

Filed: August 18, 2000

For: METHODS AND SYSTEMS FOR LUBRICATING DENTAL APPLIANCES

Examiner: NICHOLAS D. LUCCHESI

Art Unit: 3732

APPELLANT'S BRIEF UNDER 37 C.F.R. § 1.192

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant offers this Appeal Brief in furtherance of the Notice of Appeal filed on August 1, 2003 in the above-referenced patent application. This Appeal Brief is submitted in triplicate as required by 37 C.F.R. § 1.192(a). Please deduct the requisite fee, pursuant to 37 C.F.R. § 1.17(c), of $330 from deposit account 20-1430, and deduct any additional fees or credit any excess fees associated with the Appeal Brief to such deposit account. Appendix A, attached hereto, contains a copy of all claims pending in this case.

REAL PARTY IN INTEREST:

All right, title, and interest in the subject invention and application are assigned to Align Technology, Inc., having offices at 881 Martin Avenue, Santa Clara, California 95050. Therefore, Align Technology, Inc. is the real party interest.

RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

STATUS OF THE CLAIMS

Claims 1-38 were originally presented in the application. Claims 1-18 were cancelled. Claims 39-56 were added by amendment. Claims 19-56 have been rejected. Claims 19-56 are the subject of this appeal. No other claims are pending.

STATUS OF AMENDMENTS

A Final Office Action was mailed on May 7, 2003. No amendment has been filed in response to the Final Office Action. A copy of all the pending claims, is provided in Appendix A attached hereto.

SUMMARY OF THE INVENTION

The present invention is related generally to the field of orthodontics and more particularly relates to methods and systems for moving a patient's teeth from an initial tooth arrangement to a final tooth arrangement for the straightening of teeth. Application filed August 18, 2000 (Application), page 1, lines 13-15. Repositioning is accomplished with a hybrid treatment system of a series of polymeric shell appliances (e.g., positioners), the surface of each having a lubricous compound. *Id.*, page 5, lines 7-10.

The appealed claims are directed at a system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement. Claim 39; Application, page 4, lines 16-23. The system comprises a plurality of dental incremental position adjustment appliances configured to be placed successively on the patient's teeth and to incrementally reposition the individual teeth

in a series of successive steps, i.e., from one arrangement, through a plurality of intermediate tooth arrangements, and to a subsequent final arrangement. *Id.*. The surface of each of the appliances is coated with a lubricant. Claim 39. The series of appliances, typically from three to twenty-five appliances, are configured to receive the teeth in a cavity, wherein the appliances each have a geometry selected to reposition the teeth from one arrangement to a subsequent arrangement. Application, page 3, lines 25-30. In particular, the series of appliances generally comprise polymeric shells having cavities, wherein the cavities of successive shells have different geometries shaped to receive and resiliently reposition teeth from the one arrangement to the subsequent arrangement. Claim 40; Application, page 4, lines 7-12.

The appealed claims are also directed to methods for repositioning teeth. Claims 45, and 52. In one method, a series of incremental position adjustment appliances are deployed in a preselected order to reposition teeth from an initial tooth arrangement to a final tooth arrangement. Claim 45; Application, page 5, lines 7-10. Each appliance is coated with a lubricious composition on the surface of the dental appliance. *Id.*, lines 10-12. A first appliance with a pre-selected geometry is placed to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement where the teeth will be incrementally positioned. *Id.*, lines 12-20. The method will further comprise one or more intermediate appliances successively placed on the teeth, where such additional appliances have geometries selected to progressively reposition teeth from the first intermediate arrangement through successive intermediate arrangement(s). *Id.* A final appliance is placed having a geometry selected to progressively reposition teeth from the last intermediate arrangement to the desired final tooth arrangement. *Id.*

Another method for repositioning teeth using appliances comprises polymeric shells coated with a lubricious composition and having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement. Claim 52; Application, page 6, lines 24-27. The improvement comprises determining at the outset of treatment geometries for at least three appliances to be used in combination with at least one wire and bracket system. *Id.*, lines 27-32. The appliances are to be worn successively by a patient to reposition the teeth from an

initial tooth arrangement to the final tooth arrangement, wherein the cavities of successive shells have different geometries. *Id.* .

The appealed claims are also directed to a method of fabricating a plurality of lubriciously coated dental incremental position adjustment appliances. Claims 19 and 22, Application, page 6, lines 3-5. One method comprises providing an initial digital data set, a final digital data set, and producing a plurality of successive digital data sets representing the target successive tooth arrangements. Claim 19, Application, page 6, lines 5-7. The method further comprises fabricating the appliances based on at least some of the digital data sets to produce successive positive models of the desired tooth arrangements. *Id.*, lines 7-11. The dental appliances are then produced as negatives of the positive models using conventional positive pressure or vacuum fabrication techniques. *Id.*, lines 11-12.

ISSUES

I. Whether claims 19-56 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,975,893 issued to Chishti et al in view of U.S. Patent No. 4,537,689 issued to Morrow et al.

GROUPING OF THE CLAIMS

Appellant submits that the claims do not stand or fall together. Independent claims 19, 22, 39, 45, and 52 each define elements patentable over the cited art. Hence, only independent claims 19, and 22 and dependent claims 20-21and 23-38 stand together; independent claim 39 and dependent claims 40-44 stand together; independent claim 45 and dependent claims 46-51; and independent claim 52 and dependent claims 53-55 stand together.

ARGUMENT

I. Whether claims 19-56 are unpatentable under 35 U.S.C. § 103(a) over Chisti et al in view of Morrow.

In the Final Office Action dated August 20, 2002, claims 19-56 were rejected under Section 103(a) as allegedly being unpatentable over U.S. Patent No. 5,975,893 issued to

Chishti et al in view of U.S. Patent No. 4,537,689 issued to Morrow et al. Appellant respectfully traverses this rejection for the following reasons discussed below.

The present rejection does not establish *prima facie* obviousness under 35 U.S.C. § 103 and M.P.E.P. §§ 2142-2143. The Examiner bears the initial burden to establish and support *prima facie* obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976). To establish *prima facie* obviousness, three basic criteria must be met. M.P.E.P. § 2142. First, the Examiner must show some suggestion or motivation, either in the Chishti et al reference or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Secondly, the Examiner must establish that there is a reasonable expectation of success for the modifications. M.P.E.P. § 2142. Thirdly, the Examiner must establish that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. §2143.03; *In re Royka3*, 180 U.S.P.Q. 580 (CCPA 1974). The teachings, suggestions, and reasonable expectations of success must be found in the prior art, rather than in appellant's disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438 (CAFC 1991).

Appellant respectfully submits that a *prima facie* case of obviousness has not been met because the Examiner's rejection fails on at least one of the above requirements, i.e. the Examiner fails to cite as motivation or suggestion, either in the cited art references or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings so as to produce the claimed invention.

Independent claim 39 reads as follows:

A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:

a first appliance having a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;

one or more intermediate appliances having geometries selected to progressively reposition the teeth from the first intermediate arrangement to successive intermediate arrangements; and

a final appliance having a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement;

wherein the surface of each appliance has a lubricious composition coupled thereto.

Chishti describes dental positioning appliances of the type claimed herein, but provides no motivation for the use of a lubricant with such dental incremental position adjustment appliances. Final Office Action dated August 20, 2002, page 3. The Examiner attempts to remedy this deficiency by combining the teachings of Morrow with the disclosure of Chishti et al. In particular, it is the Examiner's position that Chishti et al describes tooth appliance systems of the type fabricated herein (which the Applicants freely concede), and that Morrow et al. provides motivation for coating the Chishti et al. appliances with a lubricious composition "to increase comfort to the wearer." *Id.*, page 4.

The Examiner's reliance on the Morrow et al. patent to teach the use of a lubricant with the tooth aligners of the present invention is misplaced. The purpose of an athletic mouth protector, as taught in Morrow et al., and the purpose of a tooth repositioning appliance, as taught by Chishti and claimed herein, are quite different. In determining obviousness, the entirety of the invention, including the properties and purposes of the invention, must be considered. *In re Wright*, 6 USPQ2d 1959 (Fed. Cir. 1988). The principle purpose of an athletic mouth guard as disclosed in Morrow et al. is to protect from and reduce forces applied to teeth from impact. This purpose is achieved through a relatively thick layer of plastic designed to distribute the force of impact so that as little force as possible is transmitted to localized areas of the teeth. Conversely, the tooth positioning devices of Chishti and the present invention are orthodontic techniques intended to move teeth, and not only allow for localized force, but require it to place teeth in proper alignment.

References can not be arbitrarily combined. There must be some reason why one skilled in the art would be motivated to make the proposed combination of references. *In re Nomiya*, 184 U.S.P.Q. 607 (CCPA 1975). Nowhere does Morrow et al. discuss the use of orthodontic techniques for moving teeth. Additionally, Chishti et al. is absent of any suggestion that providing a lubricous coating or reducing friction between the appliance and the underlying teeth would be desirable. The only source suggesting the desirability of increasing the comfort

of the Chishti et al. appliances is found in the present application, e.g. at page 19 lines 21-25. Reliance on the present application, however, for explaining the desirability of combining the prior art is expressly forbidden by the MPEP and underlying case law.

The Examiner asserts that "a lubricant as disclosed by Morrow et al would do nothing to prevent the appliance from remaining on the teeth..." *Id.* This assertion can only be gleaned from hindsight, as the combination of the lubricated mouth guard of Morrow et al. with the tooth aligners of Chishti et al. is in fact contraindicated by the references. Because the mouth guard of Morrow et al. is intended to **shield from and dissipate force** to the teeth from unintentional trauma and movement caused by impact to the mouth, it is advantageous that the mouth guard be able to slide freely relative to the teeth. In contrast, the aligners of the '893 patent are intended to **move teeth by imparting a constant repositioning force** to them. In particular, Chishti et al. uses a plurality of polymeric shell appliances which engage the teeth by friction to transmit an elastic recoil force to move the teeth. Because of this frictional element, the use of a lubricant on such tooth repositioning appliances is counter intuitive, and prior to the present invention, one skilled in the art would have questioned whether or not the aligners could be effective when lubrication is used. While the present invention has determined that tooth positioning devices in fact can be effective when lubricated, nothing in the prior art would have taught or suggested this result. Therefore, the Examiner's combination of the two references and determination that a lubricant "would do nothing to prevent the appliance from remaining on the teeth" can only be the product of impermissible hindsight reconstruction.

The appellant also notes that the art cited in Morrow et al. and Chisti et al. are non-analogous. Morrow et al. concerns athletic mouth protectors "to guard against injury to teeth, gums and other structures of the oral cavity." Col. 1, lines 10-12. The product of the Morrow et al. patent is purchased over-the-counter, and are generally made to be "one size fits all." In contrast, the product of Chishti et al. is an orthodontic appliance designed to reposition teeth into proper alignment. The aligners of Chishti are individually generated for each patient, and are only prescribed by orthodontists. Therefore, one skilled in the art of repositioning teeth would not be motivated to combine art from a different technical field such as athletic protectors.

Independent claim 45 is an improved method directed to repositioning teeth from an initial tooth arrangement to a final tooth arrangement. In particular, the improved method also uses incremental position adjustment appliances coupled with a lubricous composition. Hence, as claim 45 includes similar limitations as those found in claim 39, prima facie obviousness of claim 45 (and dependent claims 46-51) has not been shown for the reasons shown above with respect to claim 39 and accordingly the claims should be allowed.

Independent claim 52 is also an improved method directed to repositioning teeth from an initial tooth arrangement to a final tooth arrangement. In particular, the improved method uses polymeric shells coupled with a lubricous composition. Hence, as claim 52 includes similar limitations as those found in claim 39, it is respectfully requested that the §103(a) rejection of independent claim 52 (and dependent claims 53-56) be withdrawn the claims be allowed for the reasons set forth above with respect to claim 39.

Similarly, independent claims 19 and 22 are directed to methods for fabricating a dental appliance. In particular, the improved methods also include incremental dental appliances coupled with a lubricous composition. Hence, as claims 19 and 22 include similar limitations as those found in claim 39, prima facie obviousness of claim 19 (and dependent claims 20-21) and 22 (and dependent claims 23-38) has not been shown for the reasons shown above with respect to claim 39 and accordingly the claims should be allowed.

Appellant points out that the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* In the instant case, the Examiner has not pointed to any evidence in the cited art references, or how knowledge of those skilled in the art, provide a suggestion or motivation to combine the reference teachings of Chishti et al. with Morrow et al. so as to produce the lubricated tooth repositioning appliances of claims 19-56. See *In re Zurko* , 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001) ([I]n a determination of patentability .... the Board cannot simply reach conclusions based on its

understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings).

Under *Vaeck*, absent any evidence of a cited suggestion or reasonable motivation in the Morrow et al. reference, or knowledge of those skilled in the art, for coating teeth repositioning appliances with a lubricious composition, *prima facie* obviousness of claims 19, 22, 39, 45, and 52 (and dependent claims 20-21, 23-38, 40-44, 46-51, and 53-55) has not been established.

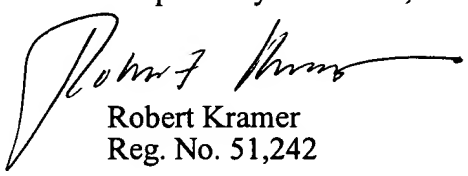
Hence, Chishti or Morrow, singly or in combination with each other, can neither anticipate nor render the invention obvious. Withdrawal of the §103(a) rejection and allowance of claims 19-56 is therefore respectfully requested.

CONCLUSION

Appellant believes that the above discussion is fully responsive to all grounds of rejection set for the in the Final Office Action dated August 20, 2002.

If for any reasons the Examiner believes a telephone conference would in any way expedite resolution of the issues raised in this appeal, the Examiner is invited to telephone the undersigned at 650-324-6340.

Respectfully submitted,



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APPENDIX A

COMPLETE SET OF PENDING CLAIMS

19. (As filed) A method for fabricating a dental appliance, said method comprising:

providing a digital data set representing a modified tooth arrangement for a patient;

controlling a fabrication machine based on the digital data set to produce a positive model of the modified tooth arrangement;

producing the dental appliance as a negative of the positive model;

applying a lubricious composition to the surface of the dental appliance.

20. (As filed) A method as in claim 19, wherein the controlling step comprises:

providing a volume of non-hardened polymeric resin;

scanning a laser to selectively harden the resin in a shape based on the digital data set to produce the positive model.

21. (As filed) A method as in claim 19, wherein the producing step comprises molding the appliance over the positive model.

22. (As filed) A method for fabricating a dental appliance, said method comprising:

providing a first digital data set representing a modified tooth arrangement for a patient;

producing a second digital data set from the first data set, wherein the second data set represents a negative model of the modified tooth arrangement;

controlling a fabrication machine based on the second digital data set to produce the dental appliance;

applying a lubricious composition to the surface of the dental appliance.

23. (As filed) A method as in claim 22, wherein the controlling step comprises selectively hardening a non-hardened resin to produce the appliance and separating the appliance from the remaining liquid resin.

24. (As filed) A method as in claim 22, wherein the appliance comprises a polymeric shell having a cavity s haped to receive and resiliently reposition teeth from an initial tooth arrangement to the modified tooth arrangement.

25. (As filed) A method as in claim 22, wherein the appliance is coated with a polar chemical to provide a hydrophilic surface.

26. (As filed) A method as in claim 25, wherein the chemical is one of hydrogels, 2-HEMA (2-hydroxy ethyl methacrylate), NVP (n-vinyl pyrolidone), or acrylyamide, PEO (polyethylene oxide) at various molecular weights, PPO (polypropylene oxide), MA (methacrylic acid), and AA (acrylic acid).

27. (As filed) A method as in claim 22, wherein the appliance is coated with a non-polar chemical to provide a hydrophobic surface.

28. (As filed) A method as in claim 22, wherein the appliance is coated with an oily substance to provide a hydrophobic surface.

29. (As filed) A method as in claim 27, wherein the oily substance is either PTFE or silicone or mineral oil.

30. (As filed) A method as in claim 22, wherein the appliance is coated with a chemical to make its surface slippery.

31. (As filed) A method as in claim 22, wherein the appliance has a surface adapted to imbibe and hold a micromolecular layer of water to lubricate the lips or the side of the mouth.

32. (As filed) A method as in claim 22, wherein the composition is applied by a spraying operation.

33. (As filed) A method as in claim 22, wherein the composition is applied using an electro-static discharge and further comprising baking the appliance.

34. (As filed) A method as in claim 22, wherein the composition is applied by a dipping operation.

35. (As filed) A method as in claim 22, wherein the surface of the appliance is pretreated.

36. (As filed) A method as in claim 35, wherein the precoating treatment includes one or more of the following: corona discharging, acid etching or solvent etching.

37. (As filed) A method as in claim 35, wherein the precoating treatment includes one or more of the following: sanding, abrasing, tumbling and sand blasting.

38. (As filed) A method as in claim 22, wherein the surface of appliance can be modified using one or more of the following: coating, grafting, laminating and interpenetrating networks.

39. (New) A system for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said system comprising a plurality of dental incremental position adjustment appliances including:

a first appliance having a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;

one or more intermediate appliances having geometries selected to progressively reposition the teeth from the first intermediate arrangement to successive intermediate arrangements; and

a final appliance having a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement;

wherein the surface of each appliance has a lubricious composition coupled thereto.

40. (New) A system as in claim 30, wherein the appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.

41. (New) A system as in claim 40, wherein the tooth positions defined by the cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.

42. (New) A system as in claim 39, comp rising at least two intermediate appliances.

43. (New) A system as in claim 42, comprising at least ten intermediate appliances.

44. (New) A system as in claim 43, comprising at least twenty-five intermediate appliances.

45. (New) A method for repositioning teeth from an initial tooth arrangement to a final tooth arrangement, said method comprising:

placing a first incremental position adjustment appliance in a patient's mouth, wherein the first appliance has a geometry selected to reposition the teeth from the initial tooth arrangement to a first intermediate arrangement;

successively replacing one or more additional appliances, wherein the additional appliances have geometries selected to progressively reposition the teeth from the first intermediate arrangement to successive intermediate arrangements; and

placing a final appliance into the patient's mouth, wherein the final appliance has a geometry selected to progressively reposition the teeth from the last intermediate arrangement to the final tooth arrangement, wherein the surface of each appliance has a lubricous composition coupled thereto.

46. (New) A method as in claim 45, wherein the appliances comprise polymeric shells having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement.

47. (New) A method as in claim 46, where the tooth positions defined by the cavities in each successive appliance differ from those defined by the prior appliance by no more than 2 mm.

48. (New) A method as in claim 45, wherein the successively placing step comprises placing at least two additional appliances prior to placing the final appliance.

49. (New) A method as in claim 48, wherein the successively placing step comprises placing at least ten additional appliances.

50. (New) A method as in claim 45, wherein the successively placing step comprises placing at least twenty-five additional appliances.

51. (New) A method as in claim 45, wherein the appliances are successively replaced at an interval in the range from 2 days to 20 days.

52. (New) An improved method for repositioning teeth using appliances comprising polymeric shells having cavities shaped to receive and resiliently reposition teeth to produce a final tooth arrangement, wherein the improvement comprises determining at the outset of treatment geometries for at least three appliances which are to be worn successively by a

patient to reposition teeth from an initial tooth arrangement to the final tooth arrangement and coating the interior of each of the polymeric shells with a lubricous composition.

53. (New) An improved method as in claim 52, wherein at least four geometries determined at the outset.

54. (New) An improved method as in claim 53, wherein at least ten geometries are determined at the outset.

55. (New) An improved method as in claim 54, wherein at least twenty-five geometries are determined at the outset.

56. (New) An improved method as in claim 52, wherein the tooth positions defined by the cavities in each successive geometry differ from those defined by the geometry by no more than 2 mm.